



SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY/DOCKET NO
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08/523,855 03/05/95 BRANSTROM

A 003/014/SAP

EXAMINER

TATE, C

ART UNIT PAPER NUMBER

1808

DATE MAILED:

10/10/96

JOHN MORAN  
U S ARMY MEDICAL RESEARCH AND MATERIAL  
COMMAND  
FORT DETRICK  
FREDERICK MD 21702-5012

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

*for restriction purposes only*  
☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made fi:

A shortened statutory period for response to this action is set to expire 1 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-94. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.      |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____  |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-44 are pending in the application  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☐ Claims \_\_\_\_\_ are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☒ Claims 1-44 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Art Unit: 1808

**Part III DETAILED ACTION**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claim 1-4, drawn to an attenuated *Shigella* strain, classified in Class 435, subclass 822, for example..

Group II. Claims 5-6, drawn to a method of producing an attenuated *Shigella* strain, classified in Class 435, subclass 172.1, for example.

Group III. Claims 7-10, drawn to a vaccine comprising attenuated *Shigella*, classified in Class 424, subclass 197.11, for example.

Group IV. Claims 11-13 , drawn to a method of reducing disease symptoms by administering attenuated *Shigella*, classified in Class 424, subclass 9.2, for example.

Group V. Claims 14-19 and 28-33, drawn to a method of delivering DNA to a cell using attenuated *Shigella*, classified in Class 514, subclass 44, for example.

Group VI. Claims 20-23 and 34-39, drawn to a method of delivering an antigen using attenuated *Shigella*, classified in Class 424, subclass 184.1, for example.

Group VII. Claims 24-27, drawn to a method of oral immunization against *Shigella*, classified in Class 424, subclass 197.11, for example.

Art Unit: 1808

Group VIII. Claim 40, drawn to a method of detecting *Shigella* infection, classified in Class 424, subclass 9.81, for example.

Group IX. Claims 41-43, drawn to a diagnostic test kit for detecting *Shigella* infection, classified in Class 435, subclass 7.2, for example.

Group X. Claim 44, drawn to a method of delivering functional nucleic acids into a cell using bacteria, classified in Class 435, subclass 252.3, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group I and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the product as claimed can be made by processes other than by the method of Group II, such as serial passaging or mutating a different *Shigella* gene to cause a loss of virulence.

3. The Inventions of Group I, III, and IX are drawn to patentably distinct products. The vaccine of Group III and the diagnostic kit of Group IX are independent and distinct from each other and do not necessarily require the attenuated *Shigella*

Art Unit: 1808

strain of Group I (a strain that dies once inside cell, or the designated *Shigella* strains of Group I - claims 2 and 3). In addition, the search required for the groups would not be co-extensive, especially with regard to the non-patented literature search.

4. Inventions of Group I and Groups IV-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in materially different processes as evidenced by the claims themselves. The product can be used in a method of reducing disease symptoms (Group IV), a method of delivering DNA (Group V), a method of delivering an antigen (Group VI), a method of oral immunization (Group VII), or a method of detecting *Shigella* infection (Group VIII).

5. The Inventions of Groups IV-VIII are drawn to patentably distinct methods independent and distinct from each other as described above. In addition, although the methods of Groups IV-VIII require an attenuated strain of *Shigella*, they do not require a *Shigella* strain of Group I (a strain that dies once inside cell, or a designated *Shigella* species or strain - claims

Art Unit: 1808

2 and 3), nor do they require the methods used in Group II to make a *Shigella* strain.

6. The method of Group X is distinct and independent from all other groups because it does not require an attenuated *Shigella* strain. It only requires bacteria which could be any bacterial genus and species other than Group I.

7. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the searches required for each of the individual groups are not required for the others, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition

Art Unit: 1808

under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Tate whose telephone number is (703) 305-7114. The examiner can normally be reached on Monday-Thursday and every other Friday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached at (703) 308-4743. The fax number of this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Christopher R. Tate

October 7, 1996



BLAINE LANKFORD  
PATENT EXAMINER  
GROUP 1800